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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,786	05/17/2005	Halina Miller-Podraza	0837-0180PUS1	6363

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EXAMINER	
LAU, JONATHAN S	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
04/25/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/501,786	MILLER-PODRAZA ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *68-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *68-83* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is responsive to Applicant's Remarks filed 17 Jan 2008. This Office Action withdraws the Requirement for Restriction/Election detailed in the Office Action mailed 27 Sep 2007 in favor of the Restriction Requirement and three Election of Species Requirements detailed in the instant Office Action.

Response to Remarks

First, the invention of claim 1 is considered to be anticipated by Angstrom et al. in light of the fact that claim 1 encompasses "**analogs or derivatives of said oligosaccharide sequence**", as long as the substance which comprises said oligosaccharide sequence has binding activity with regard to *Helicobacter pylori*. Angstrom et al. discloses the compound Gal-alpha3-Gal-beta4-Glc-beta1-Cer (page 299, table 1, compound 12 isotglobotri), an analog or derivative of a substance which comprises said oligosaccharide sequence has binding activity with regard to *Helicobacter pylori*. The scope of claim 1 is being read to include the compound Gal-alpha3-Gal-beta4-Glc-beta1-Cer, a substance which comprises an analog or derivative of said oligosaccharide sequence, in light of the fact that the claim recites a chemical structure using the open language of "comprising terminal oligosaccharide sequence". Therefore, claim 1 encompasses substances which comprise analogs and derivatives of said oligosaccharide sequence, such as Gal-alpha3-Gal-beta4-Glc-beta1-Cer disclosed by Angstrom et al.

Therefore, Applicant's Remarks regarding the Lack of Unity based on Angstrom et al. are not persuasive as discussed above; and the Lack of Unity based on Angstrom et al. is found to be proper.

However, interpretation of claim 73 indicates that claim 73 is drawn to as a method of making a pharmaceutical composition comprising said Helicobacter pylori binding substance based on the language "Use of a Helicobacter pylori binding substance ... for the production of a pharmaceutical composition...", and claim 73 should have been be properly grouped with the invention of Group I, and interpretation of claim 77 indicates that claim 77 is drawn to "The substance according to claim 68" and recites an intended use of the substance, and claim 77 should have been be properly grouped with the invention of Group I. Accordingly, the Requirement for Restriction/Election detailed in the Office Action mailed 27 Sep 2007 is withdrawn in favor of the Restriction Requirement and three Election of Species Requirements detailed in the instant Office Action.

Restriction Requirement

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 68-77, 79, 80 and 81, drawn to a Helicobacter pylori binding substance comprising the terminal oligosaccharide sequence

$[Hex1(A)_{q1}(NAc)_{r1}\alpha/\beta3]_sGal(NAc)_{r2}\beta4Glc(A)_{q2}(NAc)_{r3}$, pharmaceutical or food compositions thereof and methods of making said pharmaceutical compositions. (See Examiner's Note)

Group II, claim(s) 82 and 83, drawn to a method for the treatment or prevention of a condition due to or caused by the presence of Helicobacter pylori wherein a pharmaceutically effective amount of said Helicobacter pylori binding substance is administered to a subject in need of such treatment.

Group III, claim(s) 78, drawn to a Helicobacter pylori binding substance bound to an oligovalent or a polyvalent carrier.

Examiner's Note
Claim 73 recites a nonstatutory "use" claim. Claim 73 has been interpreted as a method of making a pharmaceutical composition comprising said Helicobacter pylori binding substance based on the language "Use of a Helicobacter pylori binding substance ... for the production of a pharmaceutical composition..."

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The common feature between the inventions of group I and II is the common core of the oligosaccharide sequence $[Hex1(A)_{q1}(NAc)_{r1}\alpha/\beta3]_sGal(NAc)_{r2}\beta4Glc(A)_{q2}(NAc)_{r3}$. However, such a sequence, when s = 0, r2 = 1, q2 = 1 and r3 = 0, is a known product. Jacquinet et al. (US Patent 4,943,630, issued 24 Jul 1990, cited in PTO-892) discloses a mucopolysaccharide fragment having 2 saccharides (abstract) made of a D-galactosamine and D-glucuronic acid (column 1, lines 40-65) linked β4 (column 4, lines 55-61), wherein the D-galactosamine derivative is N-acetyl (column 6, lines 48-56). Therefore the common feature does not serve as the special technical feature of a single general inventive concept. The special technical feature of the invention of Group I is the specific chemical structure of a Helicobacter pylori binding substance comprising the terminal oligosaccharide sequence. The special technical feature of the invention of Group II is the specific method of treating a specific disease wherein a pharmaceutically effective amount of said Helicobacter pylori binding substance is administered to a subject in need of such treatment. The special technical feature of the invention of Group III is the specific chemical structure of a Helicobacter pylori binding substance bound to an oligovalent or a polyvalent carrier.

Election of Species Requirements

If Applicant elects the invention of Group **I** or **II**, Applicant is further required to elect from Election of Species **a)** and **b)**.

If Applicant elects the invention of Group III, Applicant is further required to elect from Election of Species **c)**.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a) Species of Helicobacter pylori binding substance, for example, the substance whose chemical structure is, in its entirety, GalNAcβ4Glc (disclosed on page 34, line 6), and

b) Species of disease to be treated, for example gastric ulcer (disclosed in claims 75 and 83), and

c) Species of Helicobacter pylori binding substance bound to an oligovalent or a polyvalent carrier as defined in claim 78 with specific elections for numbers l and n and groups R_1-R_{10}, X, Y, and Z.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is cautioned that election of a genus of compounds, for example electing for species a) "A Helicobacter pylori binding substance comprising a terminal oligosaccharide sequence of GalNAcβ4Glc", will be considered non-responsive. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An

argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

All claims are generic to the species of Helicobacter pylori binding substance and the species of disease to be treated.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As recited above, the common feature between the inventions of Group I-III is the common core of the oligosaccharide sequence $[Hex1(A)_{q1}(NAc)_{r1}\alpha/\beta3]_sGal(NAc)_{r2}\beta4Glc(A)_{q2}(NAc)_{r3}$. However, such a sequence, when s = 0, r2 = 1, q2 = 1 and r3 = 0, is a known product. Jacquinet et al. (US Patent 4,943,630, issued 24 Jul 1990, cited in PTO-892) discloses a mucopolysaccharide fragment having 2 saccharides (abstract) made of a D-galactosamine and D-glucuronic acid (column 1, lines 40-65) linked β4 (column 4, lines 55-61), wherein the D-galactosamine derivative is N-acetyl (column 2, lines 35-40). Therefore the common feature does not serve as the special technical feature of a single general inventive concept. The special technical feature of each group is as recited above.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product

are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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